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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT*	ATTY. DOCKET NO.
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EXAMINER

ATTORNEY PAPER NUMBER

DATE MAILED:

This is a communication from the examiner in charge of your application
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11, 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 9 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-19 is/are pending in the application
- Of the above, claim(s) 9-15 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-8 & 16-19 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d)
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☒ received
- ☐ received in Application No. (Series Code:Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e)

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 272
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-8 and 16-19, drawn to an alpha-amylase, a method for producing the amylase by cultivating a *Bacillus* strain and a detergent composition comprising the amylase, classified in Class 435, subclass 202 and Class 510, subclass 392.

II. Claims 9-15, drawn to a DNA sequence, an expression vector comprising the DNA, a cell comprising the DNA and a method for making the amylase comprising using the transformed cell, classified in Class 435, subclasses 202, 320.1, 252.31, 252.33 and Class 536, subclass 21.2.

The inventions are distinct, each from the other because of the following reasons:

The enzyme of Group I and the DNA of Group II are chemically distinct compounds and are therefore patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Rena Green on February 11, 2000 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-8 and 16-19. Affirmation of this election must be made by applicant in responding to this Office action. Claims 9-15 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

The disclosure is objected to because of the following informalities:

On page 5, lines 1-2 it is stated that the "optimum activity [is] at about 550C". Looking at Figure 2 it is apparent that the optimum activity is at 500C, not 550C.

Appropriate correction is required.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1-8 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Patent claims must indicate the intervention of "the hand of man". The instant claims read in the enzyme as it appears in nature. Claiming an "isolated alpha-amylase" or some similar recitation would overcome this rejection.

Claims 1, 4, 5 and 18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is incorrect in the recitation of "analogue" on line 8. This is the British spelling and this is a U.S. patent application. The claim is also indefinite in the recitation of "and/or" on line 11. It is not clear whether all three of the changes indicated are intended or only one.

Claim 4 is indefinite in the recitation of "preferably" on line 1. It is not clear whether this is meant to be a limitation on the claim are simply an example.

Claim 5 is indefinite in the recitations of the abbreviations "STPP" and IAS are not defined. The claim is also incorrect in the recitation of "Na₂SO₄", "Na₂CO₃", "Na₂Si₂O₅" which should apparently be "Na SO₄", "Na CO₃", "Na Si O₅".

Claim 18 is confusing and indefinite in that it depends from itself. The claim is also indefinite in the recitation of "preferably..." It is not clear whether this is meant to be a limitation on the claim are simply an example.

Claim 5 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 5 claims retention of >90% activity under certain conditions at 25°C and <90% activity at 30°C. There is apparently no teaching of the activity of the enzyme under these conditions in the instant specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed

publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Mitsugi, et al. (A) or Boyer, et al. (B or C). Mitsugi, et al. teach an alpha amylase from *Bacillus subtilis* AJ-3255 that has an optimal pH of 9 at 400C and is effective between pH 6 and 11 at 400C (column 3, lines 47-53). Boyer, et al. (B) teach an alpha amylase from a new species of *Bacillus* (column 1, lines 30-32) that has a "maximum activity at pH 9 to pH 9.2 and at about 500C" (column 4, lines 24-25). Boyer, et al. (C) teach a amylase with a pH optima of 9.2, *Bacillus* species B-3381. It is maintained that these enzymes are the enzyme of the instant claims, absent very convincing proof to the contrary. It is noted that it is not clear that the conditions of assay are the same. Also, in Boyer, et al. (B) and presumably Boyer, et al. (C) the assay was done at 500C, in Mitsugi, et al. it was done at 400C while in the instant specification it was done at 370C. It is further noted that in the instant specification assay were not done every 1/2 degree and thus the shape of Figure 1 cannot be readily

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compared with Figure 4 in Mitsugi, et al. It is pointed out that sequencing of an enzyme does not affect the patentability of that enzyme.


Claims 8 and 17-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Mitsugi, et al. (A) or Boyer, et al. (B or C). Amylases are widely known to be useful in detergent compositions and it would have been obvious to one of ordinary skill in the art to place the enzyme of the instant references in a detergent composition, absent unexpected results. The motivation would have been to obtain a detergent composition that was effective at alkaline pH. The use of amylases in detergents is taught in Mitsugi, et al. in column 1, lines 61-62 and in Boyer, et al. in column 1, lines 9-11.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., Ph.D. whose telephone number is (703) 308-1824. The examiner can normally be reached on any day of the week from 7:30 AM until 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Patterson
February 28, 2000


CHARLES L. PATTERSON, JR.
PRIMARY EXAMINER
GROUP 1800